IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

AVENTIS PHARMA DEUTSCHLAND GMBH and
KING PHARMACEUTICALS, INC.,
Plaintiffs

v. **Civil Action No. 2:05cv421**

LUPIN LTD. and
LUPIN PHARMACEUTICALS, INC.
Defendants.

MEMORANDUM OPINION AND ORDER

Presently before the Court is a motion for summary judgment by Plaintiff Aventis Pharma Deutschland GMBH ("Aventis") and Plaintiff King Pharmaceuticals ("King") (collectively referred to as "Aventis/King"). For the reasons stated herein, subject to a determination of the validity of the '722 patent, this Court **FINDS** that Lupin's proposed generic product infringes under the doctrine of equivalents the invention used to treat high blood pressure protected by U.S. Patent No. 5,061,722 (the '722 patent), namely "ramipril substantially free of other isomers."[1] Accordingly, Aventis/King's motion for summary judgment on infringement is **GRANTED** subject to the condition that the '722 patent is found valid and Lupin's cross motion for summary judgment is **DENIED** subject to the same condition. The Court emphasizes that it makes these determinations without concluding whether or not the '722 patent is valid. Indeed, while it is finding for

[1]Lupin Ltd. and Lupin Pharmaceuticals, Inc. are the defendants in this case. The Court refers to them collectively as "Lupin."

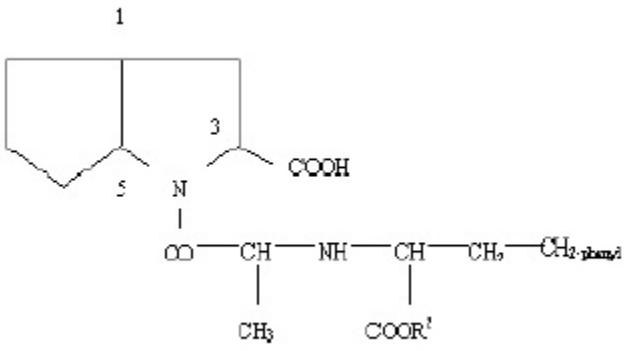
Aventis/King in this instance, this in no way affects the validity or invalidity of the '722 patent.

I. Background

This action arose on July 19, 2005 when Aventis/King brought a two-count suit against Lupin for patent infringement and inducement of infringement with respect to the '722 patent. Prior to this time, on March 18, 2005, Lupin submitted an "Abbreviated New Drug Application" ("ANDA") with "Paragraph IV certification" to the Food and Drug Administration (FDA) seeking approval to market generic versions of ramipril capsules. Pursuant to 35 U.S.C. § 271(e)(2)(A), this filing allowed Aventis/King to bring "a legal action for patent infringement before the generic drug maker has begun marketing [the drug]." SmithKline Beecham Corp. v. Geneva Pharm., Inc., 287 F. Supp.2d 576, 582 (E.D. Penn. 2002). If the original patent owner brings suit, as Aventis did here, "then [FDA] approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, which ever first occurs." Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 677-78 (1990).

The '722 patent has the following five claims:

1. A compound of the formula



> or a physiologically acceptable salt thereof, wherein R2 is hydrogen, methyl, ethyl, or benzyl, and wherein hydrogen atoms on the ring carbon atoms in the 1- and 5-positions are in the cis-configuration relative to one another, the carboxyl group on the ring carbon atom in the 3 - position is in the endo position relative to the bicyclic ring system, and the chirality centers in the chain and on the ring carbon atom in the 3-position all have the S-configuration, said compound or salt being substantially free of other isomers.

2. A compound or salt as in claim 1 which is N-(1-S-carboethoxy-3-phenyl-propyl)-S-alanyl-cis,endo-2-azabicyclo-[3.3.0]-octane-3-S-carboxylic acid or a salt thereof.

3. A compound or salt as in claim 1 which is N-(1-S-carboxy-3-phenyl-propyl)-S-alanyl-cis,endo-2-azabicyclo-[3.3.0]-octane-3-S-carboxylic acid or a salt thereof. [Note: this claim is not at issue in this case.]

4. A hypotensive composition for reducing blood pressure comprising a hypotensively effective amount of a compound or salt as in claim 1 and a pharmaceutically acceptable excipient therefor.

5. A method for reducing blood pressure in a patient which comprises administering to said patient a hypotensively effective amount of a compound or salt as in claim 1.

On May 5, 2006, this Court held a Markman Hearing. On May 11, 2006, this Court entered a claim construction order construing the terms "a compound" and "said compound or salt being substantially free of other isomers" found in claim 1 of the '722 patent. See Claim Construction Order Dated May 11, 2006 (Doc. 93). It found that "a compound" is "a fairly broad term meaning a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and definite structural arrangement." Id. at 1. It also found that "said compound or salt being substantially free of other isomers" means that "ramipril, the 'said compound,' is largely but not necessarily free of other isomers. In other words, 'substantially free

of other isomers' qualifies the compound by indicating that it may not be 100% pure or 100% free of other isomers." Id. at 2.

On May 17, 2006, Aventis/King submitted the motion for summary judgment now before the Court. Lupin responded and filed a cross-motion for summary judgment on May 26, 2006. Aventis/King filed their reply in support of their motion for summary judgment and opposition to Lupin's cross-motion on May 31, 2006. The matter is therefore ripe for judicial determination.[2]

II. Undisputed Facts

Fact No. 1: Lupin filed Abbreviated New Drug Application ("ANDA") No. 77-626 with the U.S. Food and Drug Administration, seeking approval to market generic versions of King's Altace® capsules ("Lupin's ramipril capsules"). Pl.'s Mot. for Summ. J. at Ex. A, Lupin Answer to Request for Admission No. 1.

Fact No. 2: The active ingredient in Lupin's ramipril capsules is ramipril. Id. at Ex. A, Lupin Answer to Request for Admission No. 4; Ex. B at LUPRAM 2031.

Fact No. 4: Lupin's ANDA protocol for manufacturing its ramipril requires an isomer concentration of, at least, 0.06% and no more than 0.5%. Id. at Ex. C at LUPRAM 003120;003246;003371; and 003555.

---

[2]The Court is aware that its Order will preclude Lupin from filing a reply in support of its cross-motion for summary judgment. The Scheduling Order issued on November 29, 2005 for this case states:

> Disposition of motions for summary judgment is left to the discretion of the court, and such motions may or may not be addressed prior to trial.

Rule 16(b) Scheduling Order ¶ 9 (Doc. 36). In addition, Local Civil Rule 56(A) provides that "[n]o motion for summary judgment shall be considered unless it is filed and set for hearing or submitted on briefs within a reasonable time before the date of trial . . . ." The trial is scheduled for June 6, 2006. Lupin filed its cross-motion for summary judgment on May 26, 2006. Given that Local Civil Rule 7(F)(1) provides that parties have eleven days to file a responsive brief and the moving party has three days in which to file a reply, the Court is well within its discretion to decide the instant motions before it without considering Lupin's reply to Aventis/King's opposition.

Fact No. 5: Lupin's ramipril capsules treat hypertension. Id. at Ex. A, Lupin's Answer to Request for Admission No. 2; Ex. B at LUPRAM 002029; Ex. E Lupin's proposed package insert at LUPRAM 002131.

III. Disputed Facts

The only fact in dispute for the purposes of this motion is Aventis/King's "Fact. No. 3":

> Lupin's ramipril capsules contain an alleged isomer of ramipril known as "Isomer-1" at a level of approximately 0.1% – in other words, 1/10th of 1%. Id. at Ex. C, LUPRAM 003210;003246;003371; and 003555. Consequently, the ramipril in Lupin's ramipril capsules is approximately 99.9% free of other isomers.

In its response, Lupin states:

> Lupin disputes portions of No. 3, in that the Isomer-1 present in its sample is not "alleged," it is required by its ANDA specification. (Declaration of Dr. Paul R. Haddad [hereinafter Haddad Decl.] ¶¶ 39, 47). Further it is the ANDA specification itself that controls how Lupin's ANDA product is made. Batches of product made pursuant to Lupin's ANDA specifications have included up to 0.5% of Isomer-1. (Haddad Decl. ¶¶ 38, 47). Lupin's ANDA product, when made, thus has between 0.06-0.5% by weight of Isomer-1. This amount is not insubstantial. (Id. ¶ 47).

Finally, in response to Lupin, Aventis/King replies as follows:

> Lupin claims that "[b]atches of product made pursuant to Lupin's ANDA specifications have included up to 0.5% of Isomer-1." (Lupin at 3). In support of this fact, Lupin cites paragraphs 38 and 47 of the Declaration of Paul Haddad. (Id.). Nowhere, however, is this alleged fact supported in the Haddad Declaration. In fact, the Certificate of Analysis relied on by Dr. Haddad as Exhibit E to his declaration shows that the content of Isomer-1 in Lupin's ramipril drug substance to be .12%. In other words, approximately 1/10 of 1%.

Accordingly, the parties dispute the amount of Isomer-1 in Lupin's proposed product. Aventis/King claims an amount of "Isomer-1" at a level of approximately 0.1%; Lupin claims an amount of 0.06-0.5%.

The Court observes that both parties appear to select from the Certificate of Analysis submitted with Lupin's ANDA application the percentages of Isomer-1 that best suit their arguments. In the "known impurities" section of the Certificate of Analysis, 0.12% of Isomer-1 is listed as being observed. The "specification" provided for with respect to Isomer-1 in the Certificate of Analysis, however, is "between 0.06 and 0.50%." The Court therefore **FINDS** that there is no real issue of material fact and that, based on Lupin's Certificate of Analysis submitted with its ANDA application, Lupin's ramipril capsules have a specification of between 0.06 and 0.50% and therefore may contain up to 0.50% of Isomer-1, although the Certificate of Analysis indicates that only 0.12% has actually been "observed" in their capsules.

IV. Analysis

A. Standard of Review

"Summary judgment is as appropriate in a patent case as in any other." Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984). Federal Rule of Civil Procedure 56(c) provides that summary judgment should be granted where "the pleadings, depositions [and] answers to interrogatories . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." In ruling on a motion for summary judgment, a court views the facts in the light most favorable to the nonmoving party. United States v. Lee, 943 F.2d 366, 368 (4th Cir. 1991). The moving party has the threshold burden of informing the court of the basis of the motion, of establishing that there is no genuine

issue of material fact, and that the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); see also Catawba Indian Tribe v. South Carolina, 978 F.2d 1334, 1339 (4th Cir. 1992).

Once the moving party satisfies this threshold showing under Rule 56(c), the burden of production, not persuasion, shifts to the non-moving party. Id. at 322-23. The non-moving party must "go beyond the pleadings and by [his] own affidavits, or by 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" Id. at 324; see also Fed. R. Civ. P. 56(e); Catawba Indian Tribe, 978 F.2d at 1339. "The plain language of Rule 56(c) mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322. "Where . . . the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, disposition by summary judgment is appropriate." Lee, 943 F.2d at 368.

B. Infringement

Under the Hatch-Waxman Act,

> [i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). As the United States Supreme Court has explained, this provision created "a "highly artificial" act of infringement to allow for subject matter jurisdiction in a district court

to resolve any disputes about infringement before the generic drug is sold. Eli Lily and Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990). Thus, while infringement exists when an ANDA application containing Paragraph IV certification is filed for the purposes of jurisdiction, filing an ANDA application is not a willful act of infringement in and of itself. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004). Rather, "[t]his highly artificial act of infringement gives rise to only a limited set of statutorily-defined consequences set forth in 35 U.S.C. § 271(e)(4)" if actual infringement is shown. Id. Accordingly, once the claims at issue have been construed,[3] to prove actual infringement, a patentee must show by a preponderance of the evidence "that an accused product or method meets every claim limitation either literally or under the doctrine of equivalents." Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005) (citing Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1273 (Fed. Cir. 2004)); Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001). Because the Court concludes that Lupin's proposed product infringes under the doctrine of equivalents, it will begin with a discussion of that doctrine first. It will then turn to its literal infringement analysis. Whether the presence of Lupin's isomer is "substantial" is a question of fact this Court is unable to determine at this time given the information before it.

1. Doctrine of Equivalents

"An accused device that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or equivalently." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1459-60 (Fed. Cir. 1998). When

[3]As noted supra, the Court construed the terms in Claim 1 at issue. See Claim Construction Order Dated May 11, 2006 at 2 (Doc. 93).

applying the doctrine, "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997).[4]

To find infringement under the doctrine of equivalents, the fact-finder must "determine whether the structural differences between the particular elements of the accused device and the asserted claim's limitations as recited in the claim and as shown in the corresponding means structures in the specification are insubstantial." Mas-Hamilton Group, 156 F.3d at 1212. In this way, "a patentee may invoke this doctrine to proceed against the producer of a device 'if it performs substantially the same function in substantially the same way to obtain the same result.'" Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir. 2004).

---

[4]In this way, the doctrine of equivalents is "limited." K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1367 (Fed. Cir. 1999).

> It cannot allow a patent claim to encompass subject matter that could not have been patented; nor can it be used to ignore the actual language of the patent. Thus, . . . the doctrine of equivalents cannot allow a patent to encompass subject matter existing in the prior art. Nor may it allow coverage of obvious, or "trivial," variations of the prior art . . . .

Id. (internal citations omitted). In addition, a "patentee may not use the doctrine to recover subject matter that has been surrendered." Id. at 1368. Under these principles, the doctrine of equivalents must therefore "remain within the boundaries established by the prior art, the scope of the patent claims themselves, and any surrendered subject matter." Id.

Here, as Claims 2, 4, and 5 depend on Claim 1, the primary question with respect to whether Lupin's Isomer-1 is the substantial equivalent to '722's patent claim limitation of being "substantially free of other isomers" is as follows: assuming that Lupin's ramipril capsules may contain up to 0.50% of Isomer-1, does Lupin's ramipril product containing Isomer-1 and the '722 patent's version of ramipril being "substantially free of other isomers" perform substantially the same function in substantially the same way to obtain the same result? The answer to this question is clearly yes.

The active ingredient in both Lupin's proposed product and Aventis/King's product is ramipril. The only difference between the two is that Lupin's proposed product contains, at best, 0.50% of Isomer-1, and Aventis/King's product is "substantially free of other isomers." Moreover, Lupin has admitted to this Court that Isomer-1 has no material effect on its proposed product. See Markman Hearing Tr. at 133-135 (Doc. 89). In other words, Lupin's product works no differently from Aventis/King's because the active ingredient – ramipril – is what matters. Lupin also admits that its product is designed to treat hypertension, just like Aventis/King's product.

Accordingly, the Court **FINDS** that Lupin's proposed ramipril product containing Isomer-1 performs substantially the same function, in substantially the same way, to achieve substantially the same result as the invention claimed in the '722 patent, which is ramipril substantially free of other isomers. Again, when making this ruling, the Court is not ruling on the validity of the '722 patent. In the Court's view, many of the arguments that apply to the significance of Isomer-1 in Lupin's product are likely to apply to the product described in the '722 patent as well.

2. Literal Infringement

Showing literal infringement first "requires a comparison of the claims to the accused

device." Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998). Then, in order to prove literal infringement, the patentee "must show that the accused device contains every limitation in the asserted claims." Id. (emphasis added). No literal infringement may be found "[i]f even one limitation is missing or not met as claimed." Id.

In this case, Aventis/King maintains that Lupin's proposed ramipril product infringes Claims 1, 2, 4, and 5 of the '722 patent. Because Claims 2, 4, and 5 depend on Claim 1, all of Aventis/King's contentions ultimately rest on whether Lupin's proposed product infringes Claim 1, which covers the compound ramipril itself.[5] With respect to Claim 1, which covers the compound ramipril, and Claim 2, which is specifically limited to ramipril, Aventis/King maintains that Lupin's proposed ramipril product is "substantially free of other isomers" under the Court's construction of the phrase. Pl.'s Mot. for Summ. J. at 3. With respect to Claim 4, Aventis/King contends that it "covers compositions for reducing blood pressure that comprise a hypotensively effective amount of a compound of Claim 1 and an excipient." Pl.'s Mot. for Summ. J. at 4. Lupin's proposed ramipril capsules meet all of the criteria in Claim 1 except that it adds Isomer 1. Isomer 1 does not affect the effects of the drug. Finally, with respect to Claim 5, Aventis/King argues that Lupin's proposed product infringes the claim because Lupin seeks FDA approval to administer its capsules to patients to treat high blood pressure and that Claim 5 indicates "a method for reducing blood pressure by administering to a patient a blood pressure lowering amount of a compound of Claim 1." Id.

Lupin, on the other hand, urges that a substance containing 0.06-0.5% by weight of Isomer-1 is not "substantially free of other isomers" even under the Court's construction of the phrase. Def.'s

[5]Claim 3 is not at issue in this case.

Opp. to Pl.'s Mot. for Summ. J. at 6. Lupin maintains that Plaintiffs "have proffered no actual evidence to support their theory that a substance that contains 0.06-0.5% by weight of Isomer-1 is one that is 'largely free' of other isomers." Id. Lupin points out that "the '722 patent specification does not use such weight percent measurements to define isomeric purity" and that "even variances which may seem small in terms of absolute number nevertheless can be significant when viewed against the background of the technology at issue." Id.

Moreover, Lupin urges that the presence of Isomer-1 prevents it from being "substantially free of other isomers." Id. at 7. It says that, with respect to impurities, "industry standards set as the threshold of significance 0.05%." Id. In particular, Lupin points to ICH Guidelines to support this contention.[6] In Lupin's view, the fact that the "FDA relied on these guidelines in commenting on the amount of Isomer-1 present in Lupin's ANDA product" undermines Aventis/King's infringement allegations. In addition, Lupin maintains that "[u]nder the test methods identified by the named inventor, Dr. Urbach, Lupin does not make a product 'substantially free of other isomers.'" Id. at 9. Lupin also contends that "Plaintiffs' failure to perform any comparative testing prevents this Court from concluding as a matter of law that Lupin's ANDA product is largely free of other isomers." Id. at 11. Finally, Lupin maintains that its "ANDA product contains Isomer-1 at levels well exceeding the detection limits of the relevant test methods." Id.

Given the parties' arguments, the bottom-line question is this: assuming that Lupin's ramipril capsules may contain up to 0.50% of Isomer-1, does this mean that its product is "substantially free of other isomers" under the Court's construction of the phrase? The Court has construed "substantially free of other isomers" as meaning "largely but not necessarily free of other

[6]The Court notes that Lupin does not explain what these guidelines are or what organization promulgates them.

isomers" and that the phrase "qualifies the compound by indicating that it may not be 100% pure or 100% free of other isomers." Lupin's Isomer-1 is clearly an "other isomer." While the percentage of Isomer-1 in Lupin's product is so small that it would seem that the only common-sense conclusion would be that its presence results in a version of ramipril "largely but not necessarily free of other isomers" and not 100% pure, the Court is concerned that there may be a question of fact as to whether one with ordinary skill in the art would conclude the amount of Isomer-1 is substantial even though it has no effect on the product. When this is the case, the Court cannot find Lupin's product literally infringes the '722 patent.

In its Order construing Claim 1, the Court indeed rejected Lupin's contention that a strict numerical limit on the amount of "other isomers" present in Aventis/King's ramipril product was necessary. See Claim Construction Order at 11-12 (noting that the United States Court of Appeals for the Federal Circuit has defined the "term 'substantial' [as] a meaningful modifier implying 'approximate,' rather than 'perfect'" in Playtex Prod., Inc. v. Procter & Gamble Co., 400 F.3d 901, 907 (Fed. Cir. 2005) (quoting Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361 (Fed. Cir. 2004) and observing that the Federal Circuit has also stated that, "ordinarily . . . 'substantially' means . . . 'largely but not wholly that which is specified' and that, like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358 (Fed. Cir. 2001)). To reach this conclusion, the Court relied on Federal Circuit precedent, the plain language in the claim, and the fact that nothing in the prosecution history compelled a different result. See id. at 12 (noting that the Playtex court emphasized that it "refused to impose a precise numeric constraint" on phrases such as "substantially uniform thickness" unless "something in the prosecution history imposed the 'clear and unmistakable disclaimer' needed for narrowing beyond

this plain language interpretation"). By arguing that 0.50% of Isomer-1 is not insubstantial, Lupin seems to urge this Court to create what would be a numerical threshold for the amount of "other isomers" allowable in ramipril. However, the Court stands by its conclusion that a numerical threshold was not necessary for the purposes of claim construction. Rather, the concern for the Court is that the amount of Isomer-1 in Lupin's product may be substantial regardless of alleged numerical thresholds.

There is no question that the amount of Isomer-1 in Lupin's proposed product is very small and it has no effect on the proposed product. Assuming the product contains the greatest amount of Isomer-1 allowed under the specification of the Certificate of Analysis, which is 0.5%, 99.5% of the proposed product is ramipril, the "active ingredient." Only 0.5% might be Isomer-1. The amount of .12% has been observed. Given these tiny amounts, it is difficult for this Court to say that this proposed product is not substantially free of other isomers, particularly as Lupin itself has admitted to this Court that Isomer-1 has no effect on its proposed product. See Markman Hearing Tr. at 133-135 (Doc. 89). The Court, however, perceives that it would not be difficult for some experts to opine that 0.5% is not a small or insubstantial amount. Indeed, one of Lupin's experts, Dr. Haddad, has done so. See Haddad Declaration ¶ 42. The Court also observes it was not particularly persuaded by Lupin's contention that small "variances . . . can be significant when viewed against the background of the technology at issue." Def.'s Opp. to Pl.'s Mot. for Summ. J. at 6. Small variances may indeed matter in some contexts, but the Court strains to see how a rational finder of fact would find that it matters in this one.[7] But, again, while this appears to be the

[7]Granted, as isomers in the ramipril product are apparently "impurities," the Court can fathom a situation where the FDA might not approve a product based on the amount of impurities present in it. But the question of FDA approval and the question of infringement are two different questions. In this case, the question is whether the amount of Isomer-1 in Lupin's proposed product is significant enough to distinguish it from being "substantially free of other isomers."

case, some very well-qualified expert would surely testify to the contrary. Accordingly, the Court declines to make such a fact determination based on the record before it.

The Court is similarly not particularly persuaded by Lupin's contention that industry standards set "as the threshold of significance 0.05%" based on unexplained "ICH Guidelines." See id. at 7. First of all, if Lupin wanted this Court to construe "substantially free of other isomers" and give it a set numerical value based on an alleged industry guideline, it should have made this argument at that Markman hearing or in its claim construction brief. Notably, neither the patent claims, the patent specification, nor the prosecution history of the patent mention such a guideline. Second, the only information the Court received about this guideline comes from Aventis/King, who explains that "ICH" stands for "The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use." Pl.'s Reply in Support of its Mot. for Summ. J. at 5.[8] The Court has difficulty accepting that an "industry standard" exists when Lupin has not explained where the standard comes from and who abides by it. Moreover, it appears that Lupin wants this court to adopt the ICH guideline based on the fact that, in 2003, the FDA

[8]The organization's website is www.ich.org (last visited June 6, 2006). Its welcome page states:

> The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.
>
> The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines . . . .

developed a "Guidance for Industry Impurities in New Drug Substances" while working with a working group of ICH. See Def.'s Opp. to Pl's Mot. for Summ. J. at Ex. J. Notably, this FDA guidance states that it "does not create or confer any rights for or on any person and does not operate to bind FDA or the public." Id. at 1. The logical eye of the needle Lupin asks this Court to thread becomes smaller and smaller by the moment. Nevertheless, while the Court is not convinced that the ICH "threshold of significance of .05%" is an industry guideline or one that is endorsed by the FDA, it is not a chemist or an expert in pharmacology. Consequently, it cannot say as a matter of fact at this time that the amount of Isomer-1 in Lupin's product is insubstantial.

For the above reasons, the Court declines to find that Lupin's proposed ramipril product literally infringes the '722 patent.

V. Conclusion

In conclusion, the Court **FINDS** that Lupin's proposed ramipril product infringes the '722 patent under the doctrine of equivalents. When making this ruling, the Court is not determining whether the '722 patent is valid. As the Court is not persuaded that Isomer-1 changes the effects of Lupin's proposed drug, then the primary question for the Court will be whether a version of ramipril being "substantially free of other isomers" as is described in the '722 patent changes the effect of ramipril in any substantial way from the ramipril allegedly taught in the alleged prior art of the '722 patent, namely the '258 patent and the Schering References. As far as the Court is concerned, there is simply nothing new or novel about Isomer-1 to distinguish Lupin's product from the '722 patent. Isomer-1 is inert with respect to this particular compound – it merely expands its volume by an incremental amount in an effort to distinguish it from another product. Similarly, Aventis/King's ramipril product being "substantially free of other isomers" appears to attempt to accomplish the same result. The Court is very familiar with such attempts to tweak a substance's

purity without changing the substance's effectiveness in order to increase its volume. By adding a little baking soda to cocaine, cocaine dealers do it all the time. They believe it is good business.

In any event, for the reasons explained supra, the Court concludes the following:

1. The Court **FINDS** that there is no real issue of material fact and that, based on Lupin's Certificate of Analysis, Lupin's ramipril capsules have a specification of between 0.06 and 0.50% and therefore may contain up to 0.50% of Isomer-1, although the Certificate of Analysis indicates that only 0.12% has actually been "observed" in Lupin's ramipril capsules.

2. Subject to a finding after the bench trial that the '722 patent is valid, this Court **FINDS** that Lupin's proposed generic product infringes under the doctrine of equivalents the '722 patent.

3. Aventis/King's motion for summary judgment on infringement is **GRANTED** subject to the condition that the '722 patent is found valid and Lupin's cross motion for summary judgment is **DENIED** subject to the same condition.

4. The Court is aware that Aventis/King wanted to reserve the right to present their infringement case at trial if the Court entered summary judgment only on the doctrine of equivalents. The Court **DENIES** this request. The Court observes to Aventis/King that a judgment is a judgment. Summary judgment has been entered finding infringement. If Aventis/King did not want summary judgment on the issue of infringement, it should not have moved for it, and Aventis/King cannot have it both ways.[9] Should Aventis/King desire to submit proof of facts on the question of literal infringement, the Court will allow it to do so at the appropriate time and when the Court feels it will be expedient to do so in order to conduct a speedy, efficient, and just trial.

The Clerk is **DIRECTED** to send a copy of this Order to all counsel of record via facsimile and U.S. mail.

IT IS SO ORDERED.

[9]The Court observes this is the same party that filed two identical complaints in two different districts at the outset of this case. See Aventis Pharma Deutschland GMBH v. Lupin Ltd., 403 F. Supp.2d 484, 490 (E.D. Va. 2005).

_____/s/_____

Robert G. Doumar

UNITED STATES DISTRICT JUDGE

June 5, 2006

Norfolk, Virginia